Lead Detect Prize

Phase 1
Information session

December 7, 2023

This session is being recorded;
the recording will be posted on **LeadDetectPrize.com**

Introductions

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Agenda

- Overview
- Challenge details
- How to enter
- Q&A

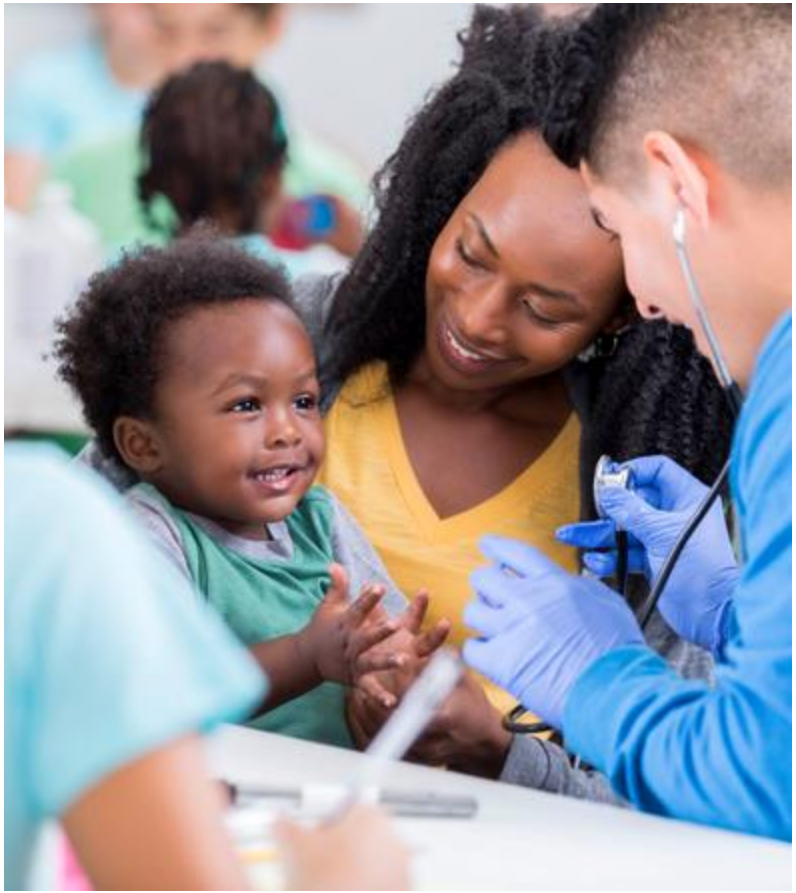
Overview

Lead Detect Prize

Prize overview

The Lead Detect Prize is a **$1 million challenge** to **enhance testing** for lead in children.

The challenge seeks to accelerate the development of **next-generation point-of-care blood lead testing technology**.



The problem

- There is **no safe level** of lead in the blood.
- Lead poisoning remains a **significant public health issue** in the United States.
- Even low levels of lead in blood are associated with **developmental delays, difficulty learning, behavioral issues,** and other harmful health effects in children.
- Lead exposure disproportionately impacts children living in communities experiencing disadvantage or poverty.

The problem

- **Point-of-care blood lead testing** is an essential tool for identifying childhood lead exposure and mitigating harmful health effects.
- All children enrolled in Medicaid should be tested for lead at ages 12 months and 24 months; despite this mandate, **roughly one-quarter of these children have not received a test** by age 3.
- Access to point-of-care testing is not uniform, but where available, it can **significantly increase rates of blood lead screening**.

The problem (continued)

- Presently, there is **only one** FDA-cleared point-of-care blood lead test performable by non-laboratory trained personnel, **first introduced in 2006**.
- In 2021, CDC issued new guidance decreasing the blood lead **reference value** from 5 µg/dL to 3.5 µg/dL.
- This has intensified the urgent need for improved technology to detect very low levels of lead exposure at the point of care.

The need for an open innovation challenge

Prize competitions *complement more traditional mechanisms (e.g., grants and contracts) to* ***catalyze breakthrough innovation****.*

Grants and contracts:

- Prescribe particular approaches or end solutions sought.
- Are awarded to an institution or organization.
- Evaluate how a proposed approach meets defined tasks.
- Fund execution of specified, approved activities.

Prize competitions:

- Encourage a variety of solution types and collaborations.
- Can be awarded to eligible individuals, teams, and entities.
- Evaluate how the work submitted meets defined criteria.
- Award flexible, non-dilutive funds and non-monetary resources that can support acceleration.

The opportunity

- **Advancements in diverse fields** — from materials science and molecular biology to microfluidics and computer science — open **new possibilities** for point-of-care blood lead testing.
- The **Lead Detect Prize** aims to foster and accelerate development of **reliable, accessible, and efficient** point-of-care testing solutions.
- Ideal solutions would be **compact, easy to use, and affordable**, facilitating expanded childhood testing and early intervention.

Lead Detect Prize

Challenge details

Challenge structure

***Phase 1** calls on **researchers and innovators** to submit **concept papers and development plans** for advanced point-of-care blood lead tests.*

CURRENT

Phase 1

November 2023 - February 2024

- Open to **all eligible entrants**.
- Technical concept papers and development plans.

PLANNED

Phase 2

February 2024 - September 2024

- Open to **Phase 1 winners**.
- Detailed designs and early evidence of performance.

Phase 1 timeline

MILESTONE 1

Phase 1 launch

November 14, 2023

MILESTONE 2 – CURRENT

Virtual information session

December 7, 2023

MILESTONE 3

Phase 1 submission deadline

January 22, 2024

MILESTONE 4

Phase 1 evaluation

January - February 2024

MILESTONE 5

Phase 1 winners announced

February 2024

Phase 2 begins

February 2024 (estimated)

Prizes

$1 million total prize pool

Phase 1

Up to five winners will receive an equal share of the **$150,000** prize pool.

Phase 2

Up to three winners will receive a share of the **$850,000** prize pool.

Phase 1 submission requirements

Proposed solutions should be capable of detecting **very low concentrations** of lead from **whole blood** samples when operated by healthcare workers **without specialized laboratory training**.

Entrants should submit **concept papers** that describe their potential solutions.

Concept papers should be a maximum of **10 pages** and include:

Content to include	Description of content to include
Concept summary	Description of proposed test and how it advances point-of-care testing using capillary blood samples.
Solution description	Method summary including scientific rationale, expected performance, and proposed pre- and post-analytical error mitigation.
Description of use	Summary of how untrained operators will use proposed test at the point of care, yielding patient- and population-level benefit.
Past progress & current status	Summary of development status, past funding, progress to date; plus initial data and FDA interactions where applicable.
Development plan	Roadmap to prototype, iterate, test/validate, and pursue clearance — including budget, timeline, and stakeholder input.
Team description	Current team areas of expertise, plus gaps or partnerships required for future development.

***Summary only**. Please **closely** review* **LeadDetectPrize.com** *for full registration and submission requirements, and additional guidelines.*

Phase 1 evaluation criteria

Submissions will be evaluated against six equally weighted criteria:

- **Analytical performance**
- **Error mitigation**
- **User-centered design**
- **Accessibility**
- **Development plan**
- **Team**

Phase 1 evaluation criteria (continued)

Criteria	Description of criteria
Analytical performance	The degree to which the proposed solution indicates potential to accurately and reliably detect low blood lead levels at the point of care. The degree to which the proposed solution includes a clear and evidence-based explanation for the scientific principle(s) underlying the solution, as well as specific and well-supported quantitative targets for analytical performance.
Error mitigation	The degree to which the proposed solution comprehensively identifies potential pre-analytical, analytical, and post-analytical sources of error and how the solution design mitigates the most significant error sources (e.g., contamination). The degree to which the proposed solution includes credible quantitative targets for accuracy and replicability, and actionable strategies to reduce overall error in future development.
User-centered design	The degree to which the proposed solution demonstrates a clear understanding of user needs, given identified point-of-care design target(s) and associated clinical workflows and environments. The degree to which the proposed solution includes user-centered rationale for design decisions to date, rationale for solution performance in the context of user needs (and considering overall challenge target performance metrics), and plans to engage clinical and patient stakeholders in future development.

Phase 1 evaluation criteria cont'd

Criteria	Description of criteria
Accessibility	The degree to which the proposed solution shows potential for broad adoption to increase rates of testing and equity of access to testing. The degree to which the proposed solution includes clear plans for addressing affordability, scalability, and other factors that would enable implementation across a wide range of geographic and socioeconomic target populations — particularly children who are currently underserved.
Development plan	The degree to which the submission describes an ambitious but achievable development plan for Phase 2 of the challenge and beyond, including a clear plan for prototyping, iteration, testing/validation, and evaluation of the test; reasonable estimates of budget requirements and resourcing opportunities beyond the challenge; and consideration of potential risks to deliver on that plan.
Team	The degree to which the team demonstrates relevant expertise, recognizes gaps, and proposes approaches to mitigate gaps to further develop the proposed solution.

TARGET PERFORMANCE METRICS

Operating parameters

Entrants should consider and address **target performance metrics** in their submissions.

In Phase 1, these metrics serve as **guidance** for what would be required of a future, hypothetical **FDA-cleared and CLIA-waived product**.

Parameter	Description of parameter
Limit of detection	Solutions should seek to reliably detect blood lead levels at or below 1.5 µg/dL.
Measurement precision	Solutions should demonstrate the potential to test blood lead concentrations spanning the reportable range that includes important decision points of 3.5 µg/dL, 20 µg/dL, and 45 µg/dL. Precision should be adequate to support the claimed measurement range.
Measurement accuracy	Solutions should indicate the ability to achieve accuracy within ±2 µg/dL or ±10%, whichever is greater, of the true blood lead concentration for 80% of samples analyzed across the reportable range.
Analysis time	Solutions should indicate the feasibility of the machine in providing results in about five minutes.
Result reporting	Solutions should be capable of electronically displaying quantitative results and directly transferring this data to electronic health information systems in formats such as HL7.
Sample collection	Solutions should minimize the required sample volume, with a target of ≤150 µL, and must use a capillary blood draw that includes steps to minimize contamination.

TARGET PERFORMANCE METRICS

Development parameters

Parameter	Description of parameter
Ease of use	Solutions should be usable by non-laboratory personnel without training, meeting the FDA criteria of waived tests as defined in 42 CFR § 493.15b.
Cost	Solutions should indicate consideration of manufacturing and per-test costs required for broad adoption.

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In Phase 1, these metrics serve as **guidance** for what would be required of a future, hypothetical **FDA-cleared and CLIA-waived product**.

Phase 1 judging

- A multidisciplinary group of judges will evaluate eligible submissions according to official Phase 1 **evaluation criteria**.
- Depending on the number of entrants, Phase 1 submissions may be initially screened by a review panel.
- Based on the judges' evaluations, judges will recommend up to five winners.

How to submit

Eligibility

The Lead Detect Prize open to submissions from individuals, teams, and entities.

Individuals

Registration: Individual registers on their own behalf

Team size: one person

Requirements: individual must meet all eligibility requirements (may be U.S. or non-U.S., not a federal employee acting in scope, not sanctioned, etc.)

Prize: awarded to the individual

Teams

Registration: Team lead registers on behalf of the team

Team size: two or more people

Requirements: Team lead must meet all individual eligibility requirements, affirm compliance on behalf of the team

Prize: single amount awarded to the team lead

Entities

Registration: point of contact registers on behalf of an entity (e.g., academic institution, company)

Team size: one or more entities; one entity plus additional individual team member(s)

Requirements: Entity must meet all eligibility requirements

Prize: single amount awarded to entity

***Summary only**. Please **closely** review* **LeadDetectPrize.com**
for full registration and submission requirements, and additional guidelines.

How to submit an entry

- Register yourself or your team on the challenge website.
- Closely read all details on the challenge website: **LeadDetectPrize.com**.
- Comply with all requirements; accept and abide by all challenge rules, terms, and conditions (detailed at **LeadDetectPrize.com**).
- Complete submission form, upload concept paper, and affirm eligibility and compliance.
- Submit by **January 22, 2024 at 4:59 p.m. EST**.

Requirements for federal grantees

Have you received other federal grant awards for your project?
If you intend to use those funds to develop your submission, several conditions must be met:

- You must register for and participate in the challenge as an entity on behalf of the awardee institution or organization.
- The use of funds for this challenge **must be consistent** with the purpose, terms, and conditions of that grant or award.
- If you are awarded a prize, it must be treated as program income for purposes of the original grant.

Federal contractors **may not** use federal funds from a contract to develop their submissions or to fund efforts in support of their submissions.

Intellectual property

Submission license policy summary:

- Participants retain intellectual property ownership of their solutions.
- Entering the challenge means granting CDC nonexclusive license to reproduce, publish, post, link to, share, create derivative works, and display publicly the submission on the web or elsewhere, throughout the world.

***Summary only**. See* **LeadDetectPrize.com** *for the full IP policy.*

Resources

- **LeadDetectPrize.com** includes curated resources related to lead exposure, blood lead testing, new test regulation and development guides, and other project resources.
- All links and resources are provided for informational purposes only.

Stay up to date

Sign up for the challenge newsletter.

Visit **LeadDetectPrize.com** for:

- Complete challenge details
- Rules, terms, and conditions
- Curated resources
- Submission platform
- News and updates

Questions

Lead Detect Prize

Thank you!

Contact:
hello@LeadDetectPrize.com

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